



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2022-0218; FRL-9593-01-OCSPP]

Toxic Substances Control Act (TSCA) Collaborative Research Program to Support New Chemical Reviews; Notice of Public Meeting and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is holding a virtual public meeting to seek individual input on the proposed Toxic Substances Control Act (TSCA) New Chemicals Collaborative Research Program. This virtual meeting will be held over 2 half days. In addition, EPA is announcing the availability of and soliciting public comment on the draft document entitled “Modernizing the Process and Bringing Innovative Science to Evaluate New Chemicals Under TSCA.” The Office of Chemical Safety and Pollution Prevention (OCSPP) is proposing to develop and implement a multi-year collaborative research program focused on approaches for performing risk assessments on new chemical substances under TSCA. This effort will be performed in partnership with the Agency’s Office of Research and Development (ORD) and other federal entities to leverage their expertise and resources. The results of the effort are expected to bring innovative science to new chemical reviews, modernize the approaches used, and increase the transparency of the information underpinning the human health and ecological risk assessment process.

DATES: *Virtual Public Meeting:* Will be held virtually on April 20 and 21, 2022, from 1:00 PM to approximately 5:00 PM (EDT) each day. See the additional details and instructions for registration that appear in Unit III.

Written Comments: Submit your written comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*]. As described in Unit III., you may also register to make oral comments during the virtual public meeting.

Special accommodations: Requests for special accommodations should be submitted on or before April 6th, 2022, to allow EPA time to process these requests.

ADDRESSES: *Virtual Public Meeting:* You must register online to receive the webcast meeting link and audio teleconference information. Please follow the registration instructions that will be announced on the New Chemicals Collaborative Research Program website available at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-collaborative> by [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. For additional instructions related to this meeting, see Unit III.

Written Comments: Submit written comments, identified by docket identification (ID) number EPA-HQ-OPPT-2022-0218, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Copyrighted material will not be posted without explicit permission of the copyright holder. Members of the public should also be aware that their personal contact information, if included in any written comments, may be posted on the internet at <https://www.regulations.gov>. Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

Due to public health concerns related to COVID-19, the EPA Docket Center and Reading Room are open to the public by appointment only. For further information on the EPA Docket Center (EPA/DC) services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

Special accommodations: For information on access or services for individuals with disabilities, and to request accommodation for a disability, please contact Sarah Swenson, listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Sarah Swenson, Office of Chemical Safety

and Pollution Prevention (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-0279; email address: swenson.sarah@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This notice is directed to the public in general. This notice may be of specific interest to persons who are or may be interested in risk assessments of new chemical substances under TSCA (e.g., submitters of TSCA 5 notices, industry, non-governmental organizations (NGOs), and academia). Since other entities may also be interested in this notice, the EPA has not attempted to describe all the specific entities that may be interested in this subject.

B. Where can I access information about this meeting?

Information about this meeting is available in the docket for this meeting, identified by docket ID number EPA-HQ-OPPT-2022-0218, at <https://www.regulations.gov>.

C. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through *regulations.gov* or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the individual listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see Tips for Effective Comments at <https://www.epa.gov/dockets>.

II. Background

A. What is the proposed TSCA New Chemicals Collaborative Research Program?

OCSPP is proposing to develop and implement a multi-year collaborative research program focused on approaches for performing risk assessments on new chemical substances under TSCA. This effort will be performed in partnership with ORD and other federal entities to

leverage their expertise and resources. The results of the effort are expected to bring innovative science to new chemical reviews, modernize the approaches used, and increase the transparency of the human health and ecological risk assessment process.

This research program will refine existing approaches and develop and implement new approach methodologies (NAMs) to ensure the best available science is used in TSCA new chemical evaluations. Key areas proposed in the TSCA New Chemicals Collaborative Research Program include:

- Updating OCSPP's approach to using data from structurally-similar chemicals to determine potential risks from new chemicals, also known as read-across. This will increase the efficiency of new chemical reviews promoting the use of the best available data to protect human health and the environment.

- Digitizing and consolidating information on chemicals to include data and studies that currently only exist in hard copy or in various disparate TSCA databases. The information will be combined with publicly available sources to expand the amount of information available, enhancing chemical reviews and enabling efficient sharing of chemical information across EPA. Safeguards for confidential business information will be maintained as appropriate in this process.

- Updating and augmenting the models used for predicting a chemical's physical-chemical properties and environmental fate/transport, hazard, exposure, and toxicokinetics, to provide a suite of models to be used for new chemicals assessments. The goal of this effort is to update the models to reflect the best available science, increase transparency, and establish a process for updating these models as science evolves.

- Exploring ways to integrate and apply NAMs in new chemicals assessments, reducing the use of animal testing. As this effort evolves, the goal is to develop a suite of accepted, fit-for-purpose NAMs that could be used by external stakeholders for data submissions under TSCA as well as informing and expanding new chemical categories.

- Developing a decision support tool that integrates the various information streams specifically used for new chemical risk assessments. The decision support tool will more efficiently integrate all the data streams (e.g., chemistry, fate, exposures, hazards) into a final risk assessment and transparently document the decisions and assumptions made. Simply put, this will facilitate the new chemicals program tracking decisions over time and evaluating consistency within and across chemistries.

Additional information on each of these key areas will be provided in draft collaborative research plan that will be available in the docket in by [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

B. How is EPA seeking public comments?

EPA is seeking public comments through several planned activities including:

- Through this ***Federal Register Notice***, EPA is announcing it intends to have a virtual public meeting on April 20 and 21, 2022, to seek individual input from the public on the proposed TSCA New Chemicals Collaborative Research Program. The agenda and instructions for registration for this meeting will be added to the EPA website and public docket [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

- At the same time, EPA will launch the website for this collaborative research program. EPA intends to make the collaborative research program document and charge questions available during the week of [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] and will issue a listserv to alert the public when these documents become available. The date the documents are added to the docket will start the official 60 days public comment period.

- Following the virtual public meeting, EPA intends to update the draft collaborative research program document as appropriate, and will place the document in the relevant docket, ID number EPA-HQ-OPPT-2022-0218.

- Later in 2022, the Agency is planning to engage the EPA's Board of Scientific

Counselors (BOSC), a federal advisory committee, for peer review; EPA also intends to issue a ***Federal Register Notice*** announcing the BOSC meeting and open a docket for public comments.

- EPA intends to solicit public comment at various points in the development and implementation of the collaborative research program, and
- Conduct additional outreach to external stakeholders through a variety of mechanisms as appropriate, to receive input and enhance transparency.

C. How can I access the documents?

EPA's background documents and the related supporting materials to the draft are available in the docket established for this meeting at <https://www.regulations.gov>; docket ID number EPA-HQ-OPPT-2022-0218. In addition, EPA will provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available, in the docket at <https://www.regulations.gov>.

After the virtual public meeting, the EPA will prepare meeting minutes summarizing the individual comments received at the meeting. The meeting minutes will be posted on the EPA website and in the relevant docket.

III. Public Participation Instructions

To participate in the virtual public meeting, please follow the instructions in this unit.

A. How can I provide comments?

To ensure proper receipt of comments it is imperative that you identify docket ID number EPA-HQ-OPPT-2022-0218 in the subject line on the first page of your request.

1. *Written comments.* The Agency encourages written comments for the virtual public meeting. Comments should be submitted using the instructions in **ADDRESSES** and Unit I.B. and C, on or before the date set in the **DATES** section. Anyone submitting written comments after this date should contact the individual listed under **FOR FURTHER INFORMATION CONTACT**. If you submit comments after the date set in the **DATES** section, those comments

will be provided to the SACC members.

2. *Oral comments.* The Agency encourages each individual or group wishing to make brief oral comments during the virtual public meeting to please follow the registration instructions that will be announced on the EPA website available at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-collaborative> by [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Oral comments during the virtual public meeting are limited to 5 minutes unless arrangements have been made prior to the date set in the **DATES** section. In addition, each speaker should email a copy of his/her comments to the individual listed under **FOR FURTHER INFORMATION CONTACT** [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] prior to the meeting.

B. How can I participate in the virtual public meeting?

This meeting is virtual and viewed via webcast. For information on how to first register and then view the webcast, please refer to the EPA website available at:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-collaborative>. EPA intends to announce registration instructions on the EPA website by [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Authority: 15 U.S.C. 2601 *et seq.*

Michal Freedhoff,

Assistant Administrator,

Office of Chemicals Safety and Pollution Prevention.

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